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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,713	02/12/2004	Nathan A. Chubb	PC10339A	7801

25533 7590 08/06/2007

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EXAMINER	
HABTE, KAHSAY	

ART UNIT	PAPER NUMBER
1624	

MAIL DATE	DELIVERY MODE
08/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,713	CHUBB ET AL.	
	Examiner	Art Unit	
	Kahsay Habte	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☒ Claim(s) *19-41* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/30/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-41 are pending in this application.

Election/Restriction

2. Applicant's election of a single disclosed species (Example 1) on 7/31/2007 is acknowledged. The examiner has searched said elected species of Example 1 and found no prior art. The search was then extended to search all of the species.

Information Disclosure Statement

3. Applicant's Information Disclosure Statement, filed on 08/30/2004 has been acknowledged. Please refer to Applicant's copies of the 1449 submitted herewith.

Claim Objections

4. Claims 2-7 are 19-41 are objected to because of the following informalities: there is no period at the end of said claims. Applicants have to insert a period after the end of claims 2-7 and 19-41.

5. Claim 19 is objected to because the term "XXX" in the middle of pages 212 and 223 is a typographical error. It is recommended that applicants remove any errors from the species recited in claims 19-41.

6. Claims 5-6 are objected to because they appear to be duplicates to one another. It is recommended that applicants review these claims.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-14 and 17-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In claims 13-14, it is recited a method of treating parasitic infestation in an animal, but the specification is not enabled for such a scope.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

The scope of the claims is not adequately enabled solely based on the activity related to antiparasitic activity provided in the specification. First, the instant claims

cover 'diseases' that are known to exist and those that may be discovered in the future, for which there is no enablement provided. There is no working example or *in vitro* data that correlates to the treatment of the diverse disorders embraced the instant claims. The disorders encompassed by the instant claims (i.e. parasitic infestation in general), some of which have been proven to be extremely difficult to treat. There is no reasonable basis for assuming that the myriad of compounds embraced by the claims will all share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art for assuming the same. Note *In re Surrey*, 151 USPQ 724 regarding sufficiency of disclosure for a Markush group.

The claims are drawn to 'treating **parasitic infestation**', however, there is no common mechanism by which all conditions due to parasitic infections arise. Parasitic infestations (infections) are extremely broad. Parasitic infections include: Amebiasis, Anisakiasis, Ascariasis, Babesiosis, Blastocystis hominis infections, Bug Bite, Cestode Infections, Chagas Disease, Cryptosporidiosis, Cyclosporiasis, Cysticercosis, Dientamoebiasis, Diphyllobothriasis, Dracunculiasis, Giardiasis, Hookworm Infections, Malaria, Scabies, Trichomonas Infections, Taeniasis, Toxoplasmosis, Whipworm Infections, etc. For more details, Applicants are directed to refer the following article downloaded from the World Wide Web: "The Merck Manual of Medical Information-Home Edition, Section 17. Infections, Chapter 184 at web site http://www.merck.com/mrkshared/mmanual_home/sec17/184.jsp".

Parasites that infect humans include protozoa (such as amebas), which consist of only one cell, and worms (helminths, such as the hookworms and tapeworms), which are larger and consist of many cells and have internal organs. Protozoa, which reproduce by cell division, can reproduce inside people. Helminths, in contrast, produce eggs or larvae that develop in the environment before they become capable of infecting people. Development in the environment may involve another animal (an intermediate host). Some protozoa (such as those that cause malaria) and some helminths (such as those that cause river blindness) have complex life cycles and are transmitted by insect vectors.

According to NIH, diseases caused by protozoan and helminth parasites are among the leading causes of death and disease in tropical and subtropical regions of the world. Efforts to control the invertebrate vector (carrier, such as the mosquito) of these diseases are often difficult due to pesticide resistance, concerns regarding environmental damage and lack of adequate infrastructure to apply existing vector control methods.

No vaccines are currently licensed to prevent or control the spread of parasitic diseases. Thus, control of these diseases depends heavily on the availability of drugs. Unfortunately, most existing therapeutics are either incompletely effective or toxic to the human host.

In a number of cases, even safe and effective drugs are failing as a result of the selection and spread of drug resistant variants of the parasites. This is best dramatized by the global spread of drug resistant *Plasmodium falciparum*, the organism responsible

for the most lethal form of malaria. New therapeutic agents are therefore urgently needed. This shows that the study is at its early stage.

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the use of the invention. In view of the breadth of the claim, the chemical nature of the invention, the unpredictability of ligand-receptor interactions in general, and the lack of working examples regarding the activity of the claimed compounds, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the invention commensurate in scope with the claims.

It is recommended that applicants delete claims 12-14 and 17-18 to overcome this rejection.

Claim Rejections - 35 USC § 112

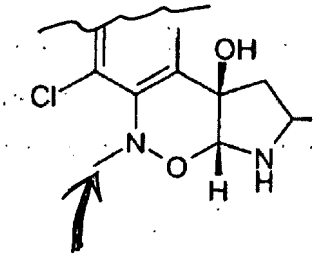
8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

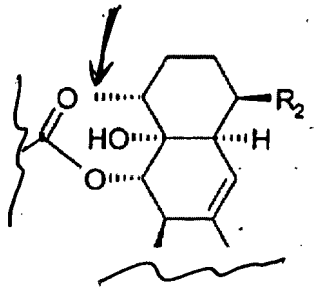
Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. Regarding claim 1 (e.g. at page 199, line 10), the phrase "including" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

b. In claim 1, two substituents that are attached to the ring nitrogen of the 1,2-oxazine ring and a substituent para to R_2 substituent are not clear. As shown below, it is unclear if the ring nitrogen is attached by H or by methyl. If it is attached by methyl, applicants have to add a CH_3 group to N instead of –.



Like wise, the carbonyl and the substituent para to the R_2 appear to be part of a



ring. Do applicants intend a hydrogen or methyl group para to the R_2 substituent? If applicants intend a methyl groups, they have to add a CH_3 group para to the R_2 substituent.

c. Claim 12 provides for the use of compound of formula (I), but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

d. Regarding claim 15, the phrase "Preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Note that this claim has twp periods. It is recommended that applicants delete this claim, since pharmaceutical composition is recited in claim 8.

e. Claim 9 is rejected because it is multiply dependent on claim 8 and claim 1.

f. In claims 8-9, 11-12 and 14-17, the phrase "solvate of either entity" is not clear. What entities?

It is recommended that applicants delete "which may adapted for topical administration from composition claims 8-9.

g. In claim 16, the phrase "for use as a parasiticide" is not clear. For use is a mental step, since it does not involve any actual steps. Note that claim 16 starts as a compound claim, but ends up as a method of use claim. If applicants intend a method

of use claim, then the claim should be written as a method of use claim. If not, claim 16 is a duplicate of claim 1.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 12 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Objection

10. Claims 19-41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kahsay Habte
Primary Examiner
Art Unit 1624

KH
August 2, 2007